

Package leaflet: Information for the patient

Korincare 20 mg prolonged-release tablets

nifedipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Korincare is and what it is used for
2. What you need to know before you take Korincare
3. How to take Korincare
4. Possible side effects
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1. What Korincare is and what it is used for

Korincare contains nifedipine, which belongs to a group of medicines called *calcium antagonists*.

Korincare is used to treat high blood pressure or angina (chest pain).

For high blood pressure: Korincare works by relaxing and expanding the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart.

For angina: Korincare works by relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your angina attacks will be less severe and less frequent if there is less strain on the heart.

2. What you need to know before you take Korincare

Do not take Do not take

- If you have had a heart attack within the last month;
- If you get a sudden angina attack. Korincare will not help relieve symptoms of angina quickly;
- If you have unstable angina;
- If you are allergic to nifedipine, any other similar medicines (known as dihydropyridines) or any of the other ingredients of this medicine (listed in section 6);
- If you are taking rifampicin, an antibiotic);
- If you have a liver disease that prevents your liver from working properly;
- If you have inflammation of the bowel or intestines, such as Crohn's disease;
- If you have an obstruction or narrowing in your intestines, or have had this in the past;

- If you have ever had an obstruction in the gullet (the oesophagus - the tube connecting the throat to the stomach);
- If you have been told that you have a narrowing of the aortic heart valve (stenosis);
- If you have ever had a collapse caused by a heart problem (cardiogenic shock), during which you became breathless, pale and had a cold sweat and dry mouth;
- If you have a “Kock pouch” (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut;
- If your blood pressure continues to rise despite treatment (malignant hypertension);

Warnings and precautions

Talk to your doctor, pharmacist or nurse, before taking Korincare.

Especially careful medical supervision is necessary:

- If you have low blood pressure and you were prescribed Korincare for your angina. Your blood pressure may be decreased further by this treatment;
- If you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve);
- If you are pregnant;
- If you are breast-feeding. If you need to take Korincare, you should stop breast-feeding before you start to take this medicine.
- If you are a diabetic. The treatment for your diabetes may need to be adjusted;
- If you are on kidney dialysis. If you have a very high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take Korincare;
- If your liver is not working properly. Your doctor may need to do some blood tests. You may also be given a lower dose of Korincare.

•Talk to your doctor before you take the next dose Korincare, if:

- your chest pain (angina) gets worse (comes on more often or more severely) over a matter of hours or days. You may be advised not to take Korincare.
- If you have chest pains after taking your first dose of Korincare. Your doctor may wish to change your treatment;
- If you notice increased breathlessness;
- If you notice swelling of the ankles.

Tell your doctor:

- If you are giving a urine sample. Nifedipine may interfere with the results of certain urine tests;
- If you are to have a barium contrast x-ray (barium meal). These tablets may affect the results of the test.
- If you are a man who has been unable to father a child by *in vitro* fertilisation. Drugs like Korincare have been shown to impair sperm function.

Other medicines and Korincare

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines.

The effect of treatment may be affected by the following active substances or groups of drugs taken concomitantly with Korincare. Tell your doctor if you are taking:

- Other medicines to treat high blood pressure;
- Rifampicin (an antibiotic);
- Cimetidine (to treat stomach ulcers);
- Digoxin, diltiazem, quinidine or beta-blockers (to treat heart conditions);
- Quinupristin/dalfopristin (a combination antibiotic);
- Phenytoin, carbamazepine or valproic acid (to treat epilepsy);
- Cisapride (to treat reduced movements of the gullet and stomach);

- Erythromycin (an antibiotic);
- Magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure);
- Ketoconazole, itraconazole or fluconazole (anti-fungal medicines);
- Indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (to treat HIV);
- Fluoxetine or nefazodone (to treat depression);
- Tacrolimus (to prevent the rejection of transplanted organs);
- Phenobarbital (usually used to treat insomnia or anxiety).

Korincare with food, drink and alcohol

You can take Korincare with or without food.

Do not start taking Korincare within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking Korincare. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You may be able to use Korincare but only after special consideration and agreement by your doctor.

Breast-feeding

Do not take Korincare if you are breast-feeding. If your doctor decides that treatment is absolutely necessary, then breast-feeding should be stopped before you start taking Korincare.

Fertility

If you are a man who has been unable to father a child by in vitro fertilisation. Drugs like Korincare have been shown to impair sperm function.

Driving and using machines

Korincare may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way. This may be more likely when you first start treatment, if you change tablets, or if you have drunk alcohol.

3. How to take Korincare

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

High blood pressure: the usual dose is 1 tablet (20 mg), once a day.

Stable angina: the dose depends on your individual requirements. Your doctor will decide how much you should take.

The duration of treatment is determined by the doctor.

When and how you should take Korincare

Swallow the tablets whole (do not bite, chew or break them), with a glass of water, with or without food. Do not take Korincare with grapefruit juice. Take your dose at the same time each day, preferably in the morning.

Use in children and adolescents

Korincare is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

If you take more Korincare than you should

Get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

Taking too many tablets Korincare may cause your blood pressure to become too low and your heartbeats to speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take Korincare

Take your normal dose immediately and continue taking your tablets at the usual time of day, waiting at least 12 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor.

If you stop taking Korincare

Do not stop taking Korincare before your doctor tells you to, even if you feel better.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately and do not take the next dose of Korincare, if you notice the following symptoms, which may be signs of a severe side effect:

- severe, sudden generalised allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway);
- other allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may result in a life-threatening outcome);
- fast heart beat (tachycardia);
- shortness of breath (frequency not known) or difficulty breathing;
- mild to moderate allergic reactions;
- itching (possibly severe), a rash or hives.

Contact your doctor immediately and do not take the next dose of Korincare, as these may be the first signs of allergic reaction which may become severe:

- a skin reaction or blistering/peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (Toxic Epidermal Necrolysis).

In addition to the above side effects, the following is a list of possible side effects, listed according to their frequency:

Common (may affect up to 1 in 10 people);

Uncommon (may affect up to 1 in 100 people);

Rare (may affect up to 1 in 1,000 people);

Not known (frequency cannot be estimated from the available data).

Common side effects:

- headache;
- flushing;
- general feeling of being unwell;
- constipation;
- swelling, particularly of the ankles and legs.

Uncommon side effects:

- abdominal pain;
- unspecific pain;
- chills;
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion);
- fainting;
- irregular heartbeat (palpitations);
- dry mouth;
- indigestion or upset stomach;
- wind (flatulence);
- feeling sick (nausea);
- muscle cramps;
- joint swelling;
- sleep disorders;
- anxiety or nervousness;
- reddening of the skin;
- nose bleeds;
- nasal congestion;
- sensation of spinning or whirling motion;
- migraine;
- dizziness;
- trembling;
- increase in the need to pass water (urinate);
- painful or difficult urination;
- impotence;
- blurred vision;
- temporary increase in certain liver enzymes.

Rare side effects:

- pins and needles;
- inflammation of the gums, tender or swollen gums, bleeding gums.

Not known side effects:

- stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal;
- difficulty swallowing;
- abdominal pain, caused by obstruction of the gut or ulcers in the gut;
- vomiting;
- a reduction in the number of white blood cells (leucopenia);
- a more severe decrease in a specific class of white blood cell (agranulocytosis);
- increased blood sugar (hyperglycaemia);
- decreased skin sensitivity (hypoesthesia);
- drowsiness (somnia);
- eye pain;
- chest pain (angina pectoris);
- heartburn or indigestion (gastroesophageal sphincter insufficiency);
- yellowing of the whites of the eyes or skin (jaundice);
- sensitivity to light (photosensitivity allergic reaction);
- small, raised areas of bleeding in the skin (palpable purpura);
- joint pain;
- muscle pain.

All of these symptoms usually go away when treatment with Korincare is stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Bulgarian Drug Agency
8 Damyan Gruev Str.,
1303 Sofia.
Tel.: +359 2 890 3417
Website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Korincare

Store below 25°C, protected from light and moisture.
Keep this medicine out of the sight and reach of children.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Korincare contains

- The active substance is: nifedipine 20 mg.
- The other ingredients are:

Core: microcrystalline cellulose, sodium starch glyconate, mannitol, sodium lauryl sulfate, silica colloidal anhydrous, povidon (type K), magnesium stearate, hydroxymethylcellulose, macrogol 6000, macrogol 400, iron oxide red (E 172), titanium dioxide (E 171), talc.

What Korincare looks like and contents of the pack:

Each pack of Korincare contains 20 nifedipine 20 mg prolonged-release tablets in 2 blisters (Alu/Alu) x 10 tablets.

Marketing Authorisation Holder and Manufacturer

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